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(54) **Detachable pusher-vasoocclusive coil assembly**

(57) A detachable pusher-vasoocclusive coil
assembly for use in occluding a selected site within a
vessel, comprising:

- (a) a pusher (12) having a proximal end, a distal
end and a single radial opening (20);
- (b) a vasoocclusive coil (13) having a proximal end

(15) and a distal end, the proximal end (15) being
capable of entering and locking into the radial open-
ing (20); and

(c) a catheter (14,21) carried coaxially about the
pusher (12) and coil (13) that is axially movable re-
lative to the pusher and coil.

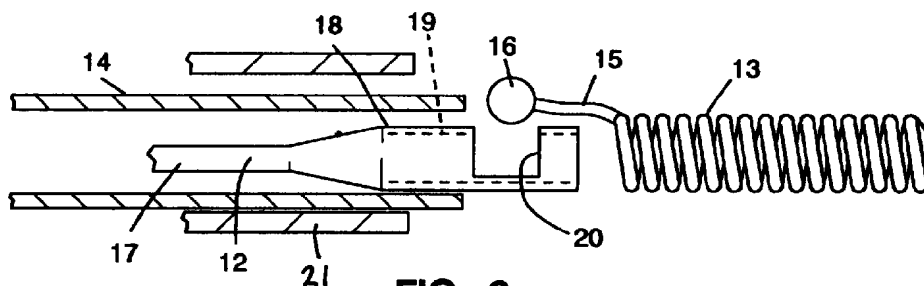


FIG. 2

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Description

The present invention is in the general field of surgical instruments and relates specifically to an apparatus for delivering a vasoocclusion coil to a selected site within a vessel (e.g., an aneurysm) via a catheter.

Vasoocclusion coils or wires are used to occlude a site, such as an aneurysm, within a vessel. The coils may be of a regular (e.g., helical) configuration or assume a random convoluted configuration at the site. Vasoocclusion coils are described in U.S. Patent No. 4,994,069. The coils are normally made of a radioopaque, biocompatible metal such as platinum, gold, or tungsten. In treating aneurysms it is common to place a plurality, typically 4 to 12, coils within the aneurysm. The coils occlude the site by posing a physical barrier to blood flow and by promoting thrombus formation at the site.

The coil(s) have typically been placed at the desired site using a catheter and a pusher. The site is first accessed by the catheter. In treating peripheral or neural conditions requiring occlusion, the sites are accessed with flexible, small diameter catheters such as the catheters described in U.S. Patents Nos. 4,739,768 and 4,813,934. The catheter may be guided to the site through the use of guidewires (see U.S. Patent No. 4,884,579) and/or flow-directed means such as balloons at the distal end of the catheter. Once the site has been accessed, the catheter lumen is cleared (i.e., the guidewire is removed if a guidewire has been used), and the coil is placed in the proximal end of the catheter and advanced through the catheter with a pusher. Pushers are wires having a distal end that is adapted to engage and push the coil distally as the pusher is advanced through the catheter. When the coil reaches the distal end of the catheter it is plunged therefrom by the pusher into the vessel. This technique of plunging the coil from the distal end of the catheter has undesirable limitations. First, because of the plunging action, the positioning of the coil at the site cannot be controlled to a fine degree of accuracy. Second, once plunged from the catheter, it is difficult to reposition or retrieve the coil if desired. Indeed, another device, called a retriever, must be threaded through the catheter to snare the coil to reposition or retrieve it.

In view of these limitations, techniques have recently been developed to enable more accurate placement of coils within a vessel. In one technique (described in U.S. Patent Application Serial No. 492,717, filed 13 March 1990) the coil is bonded via a metal-to-metal joint to the distal end of a pusher made of a different metal than the coil. The coil-carrying pusher is advanced through the catheter to the site and a low electrical current is passed through the pusher-coil assembly. The current causes the joint between the pusher and coil to be severed via electrolysis. The pusher may then be retracted leaving the detached coil at an exact position within the vessel. In addition to ena-

bling more accurate coil placement, the electric current may facilitate thrombus formation at the coil site. The only perceived disadvantage of this method is that the electrolytic release of the coil requires a given time period so that rapid detachment of the coil from the pusher is not possible. In another technique the confronting ends of the pusher and coil are designed such that the pusher clamps onto the wire and holds it until the clamp is released. Accordingly, this methodology utilizes a mechanical detachment mechanism rather than an electrolytic mechanism.

A primary object of the present invention is to provide an alternative mechanical means for detaching a vasoocclusive coil from a pusher at a desired vessel site.

According to the present invention there is provided a detachable pusher-vasoocclusive coil assembly for use in occluding a selected site within a vessel, comprising:

- (a) a pusher having a proximal end, a distal end and a single radial opening;
- (b) a vasoocclusive coil having a proximal end and a distal end, the proximal end being capable of entering and locking into the radial opening; and
- (c) a catheter carried coaxially about the pusher and coil that is axially movable relative to the pusher and coil.

Embodiments of apparatus in accordance with the present invention will now be described, by way of example only, with reference to the following drawings.

Figure 1 is an enlarged, sectional elevational view of an embodiment of the pusher-vasoocclusive coil assembly of the invention showing the pusher and coil coupled.

Figure 2 is an enlarged sectional view of the assembly of Figure 1 and a catheter showing the pusher and coil uncoupled.

Figure 3 is an enlarged perspective view of the distal end of the pusher of Figure 1.

In the drawings proximal is left and distal is right. Only the distal portions of certain elements of the assembly are depicted in the drawings.

The assembly, generally designated 11, shown in the drawing comprises three principal parts: (a) a pusher 12; (b) a vasoocclusive coil 13; and (c) a sleeve 14.

Coil 13 is shown in Figure 1 as a uniform diameter helical coil wire. It may, however, have another regular configuration or have a random configuration. In any event, the coil must be dimensioned to be able to be advanced through a catheter that is sized to access the desired site. The coil is made of a radioopaque, biocompatible metal such as platinum, gold or tungsten so that its location within the vessel may be viewed radiographically.

For use in occluding peripheral or neural sites the

coils will typically be made of 0.05 to 0.15 mm diameter platinum wire that is wound to have an inner diameter of 0.15 to 0.96 mm with a minimum pitch (i.e., the windings are close or tight). The length of the wire (wound) will normally be in the range of 0.5 to 60 cm, preferably 2 to 20 cm. As indicated, if desired, the coil may be formed so that the coil takes an essentially linear configuration in which it may be advanced through the catheter and assume a randomly oriented relaxed condition after it is released from the catheter (see U.S. Patent No. 4,994,069).

A proximal segment 15 of the coil (or a separate wire affixed to the proximal end of the coil) is deformed so that it extends proximally of the windings of the coil. The tip of segment 15 carries a sphere or ball 16. The ball may be positioned centrally relative to the segment or be offset from the axis of the segment. The length of segment 15 will normally be 0.25 to 1.2 mm and the diameter of ball 16 will normally be 0.2 to 1 mm. Segment 15 should be deformable so that ball 16 may be manipulated into engagement with the pusher as described below. Further, it is preferred that segment 15 be normally biased radially so that it will assume the position shown in Figure 2 when not constricted.

Pusher 12 comprises a proximal end segment (not shown) that provides the means by which the pusher may be gripped and manipulated, a main central core 17 and an enlarged cylindrical tip 18. Tip 18 has an axial bore 19 of at least about the diameter of ball 16 and a radial slot or keyway 20 that intersects bore 19 and has dimensions that are adapted to receive ball 16. If desired the tip may also have an axial slot extending from its distal end to the radial keyway that is dimensioned to receive segment 15. The outer diameter of tip 18 is dimensioned to be slidably received within the lumen of the enclosing means and to permit segment 15 and ball 16 to be positioned within keyway 20. (See Figure 1.)

The entire length of the pusher will be such as to be capable of being advanced entirely through the catheter 21 to the vessel site with a sufficient portion of the proximal end of the pusher protruding from the proximal end of the catheter to enable the pusher to be manipulated. Typically, the core segment will constitute at least about 90-95% of the entire length of the pusher. For use in peripheral or neural surgeries, the pusher will normally be about 100 to 200 cm in length, more usually 160 to 180 cm in length. The diameter of the core 17 of the pusher will typically be in the range of 0.25 to 0.90 mm.

The ball 16 is maintained within the keyway by radially enclosing it. The means for coaxially enclosing the thus coupled pusher and coil may be the inner wall of the catheter that is used to access the site. However, if (a) the catheter is too elastic radially to maintain the engagement or (b) it is desired to maintain the engagement distally of the distal end of the catheter, a separate sleeve 14 that is received coaxially about the coil and pusher may be employed.

The outer diameter of sleeve 14 is such that the sleeve can be advanced through the lumen of catheter 21. Correspondingly, the inner diameter of the sleeve is sized such that it can receive the coil and pusher in coupled relationship and be able to move axially relative thereto. For use in peripheral and neural surgeries the inner diameter of the sleeve will typically be 0.3 to 1 mm. The sleeve may be made of flexible plastics that can be navigated through the catheter 21.

Assembly 11 is used to place one or more vasoocclusive coils at a selected site in a vessel as follows. The pusher and coil are assembled as shown in Figure 1 with the ball 16 within keyway 20. If a sleeve is used to enclose the ball and keyway, the coupled assembly is inserted into the sleeve 14. Catheter 21 is inserted and navigated through the vessel lumen (not shown) to the site to be occluded (e.g., on an aneurysm, vascular malformation, or arteriovenous fistula). As indicated previously, conventional catheter insertion and navigational procedures involving guidewire and/or flow-directed means may be used to access the site with the catheter. Once the distal end of the catheter is positioned at the site (its location may be determined by coating the distal end of the catheter with a radioopaque material or otherwise affixing such a material to the distal end of the catheter), the catheter is cleared (i.e., if a guidewire has been used to position the catheter, it is withdrawn from within the catheter) and the pusher and coil assembly 11 is advanced through the catheter. (See Figure 2.) The assembly is advanced distally of the distal end of the catheter so that the ball and keyway are free of the catheter with the coil positioned exactly at the desired site. If a sleeve is used, the sleeve is then retracted (moved axially in the proximal direction) so that it no longer encloses the keyway and ball. The radial bias exerted by the wire 15 causes the ball 16 to move out of the keyway and the coil to be uncoupled from the pusher. (See Figure 2.) It will be appreciated that it is not essential that the wire 15 exert a radial bias and that the uncoupling may be achieved simply by gravity or fluid flow at the site. If additional coils need to be placed at the site, the pusher and sleeve are withdrawn and the procedure is repeated. After the desired number of coils have been placed at the site, the catheter is withdrawn from the vessel.

Claims

1. A detachable pusher-vasoocclusive coil assembly for use in occluding a selected site within a vessel, comprising:
 - (a) a pusher (12) having a proximal end, a distal end and a single radial opening (20);
 - (b) a vasoocclusive coil (13) having a proximal end (15) and a distal end, the proximal end (15) being capable of entering and locking into the radial opening (20); and

(c) a catheter (14,21) carried coaxially about the pusher (12) and coil (13) that is axially movable relative to the pusher and coil.

2. The assembly of claim 1, wherein the vasoocclusive coil (13) has a wire immediately distal to the coil proximal end (15). 5
3. The assembly of claim 1 or claim 2, wherein the proximal end (15) of the vasoocclusive coil (13) is generally spherical in shape. 10
4. The assembly of any one of the preceding claims, wherein the radial opening (20) includes an axial slot extending from the distal end of the pusher to the opening (20). 15

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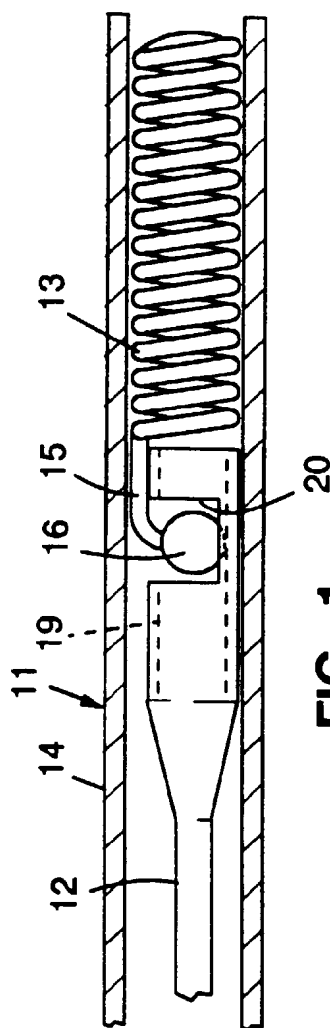


FIG. 1

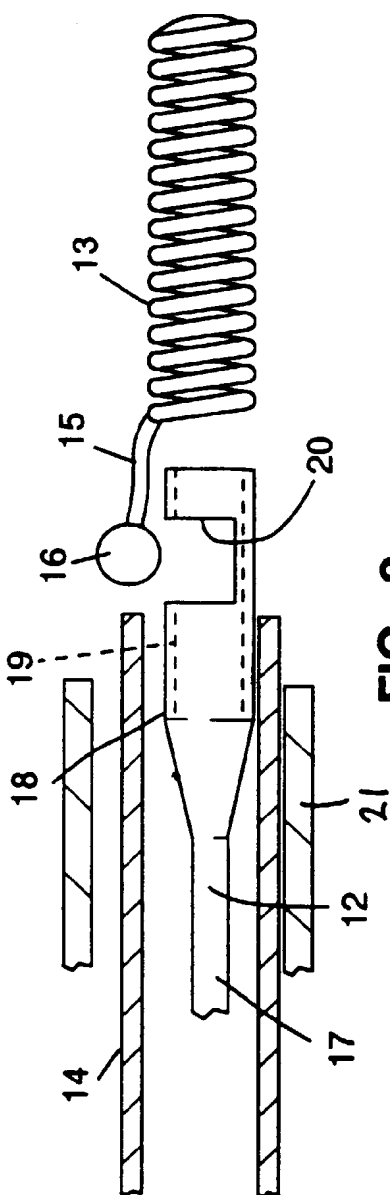


FIG. 2

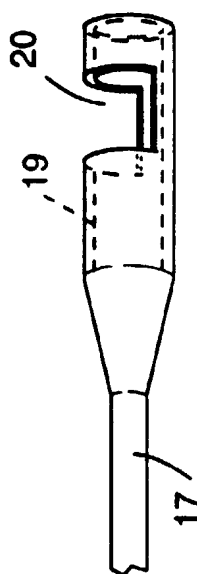


FIG. 3



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EUROPEAN SEARCH REPORT

Application Number
EP 98 10 3908

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
A	US 4 994 069 A (RITCHART ET AL.) 19 February 1991 * abstract; figures 1,2A-C * -----	1-4	A61M25/12 A61B17/00
			TECHNICAL FIELDS SEARCHED (Int.Cl.6)
			A61B
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 28 May 1998	Examiner Michels, N
<p>CATEGORY OF CITED DOCUMENTS</p> <p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p> <p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document</p>			

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